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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,458	05/08/2001	Y. Tom Tang	PF-0636 USN	4361

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,458	TANG ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-42* is/are pending in the application.

4a) Of the above claim(s) *32-34 and 38-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23,26-28,30,35 and 37* is/are rejected.

7)☒ Claim(s) *22,24,25,29 and 36* is/are objected to.

8)☒ Claim(s) *21-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/07/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 21-42 are pending in the instant application. Claims 21 and 30 have been amended as requested by Applicant in the Paper filed Sept. 7, 2004.

Claims 32-34 and 38-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 21-31 and 35-37 are currently under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.1 Claim 37 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 37 encompasses a method for treating a disease or condition associated with decreased expression of functional HCSRP, comprising administering to a patient in need of such treatment a composition comprising the polypeptide of SEQ ID NO: 12, a biologically active fragment thereof that binds

an extracellular ligand, or a polypeptide comprising at least 95% identity to the amino acid sequence of SEQ ID NO: 12 that binds an extracellular ligand.

Applicants have overcome the rejections under 35 U.S.C. 101 and 112, as far as the protein of SEQ ID NO: 12 has been demonstrated to have the activities of binding ICAM3 and being a virus attachment and presentation factor, and so has a specific and substantial utility and is enabled for use for those activities. However, claim 37 is drawn to a method of treating a disease or condition associated with decreased expression of the functional protein of SEQ ID NO: 12, comprising administering to a patient in need of such treatment a composition comprising the claimed polypeptides. However, the specification does not disclose any disease or condition associated with decreased expression of the protein of SEQ ID NO: 12. There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988). It is acknowledged that the level of skill in the art is high. However, the prior art does not teach any disease or condition associated with decreased expression of CD209L (also known as DC-SIGNR and L-SIGN), and the specification does not provide any working examples of such diseases or conditions, and little guidance. There are no examples of altered expression or correlation with any disease or disorder. Thus, the specification fails to teach the skilled artisan how to use the polypeptides therapeutically without resorting to undue experimentation. The

specification has not provided the person of ordinary skill in the art the guidance necessary to be able to use the polynucleotide for the above stated purposes.

Due to the large quantity of experimentation necessary to determine if the polypeptides could be used therapeutically, the lack of direction/guidance presented in the specification regarding same, lack of working examples and the teachings of the prior art and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention. What Applicant has provided is a mere wish or plan and an invitation to experiment.

3.2 Claims 21, 23, 26, 27, 28, 30, 35 and 37 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous office actions, Paper No. 15 at pages 8-10 and Paper No. 18, at pages 14-15, the Paper mailed May 4, 2004 at pages 17-21, and below.

Applicants traverse the rejection on pages 12-13 of the response, and have amended the claims to recite that the polypeptide binds an extracellular ligand, and point to pages 1 (binding ligand) and pages 20, 21, and 22 (95% sequence identity) of the specification for support for the amendments. Applicants also assert that the specification does provide sufficient distinguishing identifying characteristics of the genus, and point to Table 2 which recites structural features common to the genus such as potential phosphorylation sites, potential glycosylation sites and various motifs, signature sequences and protein domains.

Applicants' arguments have been fully considered but are not deemed persuasive. The specification teaches a general binding to ligands or other proteins, and does not disclose the specific ligand the protein of SEQ ID NO: 12 would bind to. Therefore, the specification does not contemplate what ligand the protein binds to, and the specification does not provide adequate support for that activity. For these reasons, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

4.1 Claims 21, 23, 26-28, 30, 35 and 37 are rejected.

4.2 Claims 22, 24, 25, 29 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER